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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,691	02/25/2002	Stephen Donovan	D-3018	5311

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[REDACTED] EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
1651	4

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/082,691	DONOVAN, STEPHEN
	<b>Examiner</b>	<b>Art Unit</b>
	Irene Marx	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_ .
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 17-19, 22 -27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is fibromyalgia pain, classified in Class 514, subclass 2, for example.

II. Claims 1-9, 11, 17-19, 22 -27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is myofascial pain syndrome pain, classified in Class 424, subclass 236.1, for example.

III. Claims 1-9, 12, 17-19, 22 -27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is arthritis pain, classified in Class 435, subclass 69.1, for example.

IV. Claims 1-9, 13, 17-19, 22-27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is migraine headache pain, classified in Class 424, subclass 94.1, for example.

V. Claims 1-9, 14, 17-27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is irritable bowel syndrome pain, classified in Class 435, subclass 239.1, for example.

VI. Claims 1-9, 15, 17-19, 22-27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is Crohn's disease pain, classified in Class 530, subclass 350, for example.

VII. Claims 1-9, 16-19, 22 -27 are drawn to a process of treating neurogenic pain with botulinum toxin and a substance P, wherein the pain is interstitial cystitis pain, classified in Class 530, subclass 412, for example.

VIII.. Claims 28 and 29 are drawn to a process of inhibiting pain with botulinum toxin attached to a substance P, classified in Class 514, subclass 12, for example.

Each of groups I and VIII is directed to separate and distinct inventions. These methods of treatment are distinct both physically and functionally, require different process steps, such as protocol of administration, including dosage, as well as the specific the component of each of the ingredients required, and produce different products/effects. Also note the differences in scope regarding the specific components.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a

reference which would anticipate the invention of Group I would not necessarily anticipate or make obvious the any of the other groups.

For these reasons restriction for examination purposes is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

*Irene Marx*  
Irene Marx  
Primary Examiner  
Art Unit 1651